

## REMARKS

Claims 124-173 are presently pending in this application. Claims 124 and 143 have been amended in this paper to clarify certain aspects of these claims. Claim 127 has been amended in independent form, and claims 128-130 have been amended to depend from claim 127. Claim 147 has been amended in independent form, and claims 148 and 149 have been amended to depend from claim 147. Claims 168-173 are new claims presented for the first time in this paper.

The Office Action dated September 15, 2004, raised several issues with respect to the claims, indicated that several claims presented allowable subject matter, and allowed several claims. More specifically, the status of the application set forth in the outstanding Office Action is as follows:

(A) Claims 124-126, 131, 132, 136-145, 150, 151 and 155-164 stand rejected under 35 U.S.C. § 102(e) over U.S. Patent No. 6,418,344 issued to Rezai et al. ("Rezai").

(B) Claims 133-135 and 152-154 stand rejected under 35 U.S.C. § 103(a) over Rezai by itself.

(C) Claims 165-167 were allowed, and claims 127-130 and 147-149 were indicated as being allowable if rewritten in independent form.

### A. Response to Section 102(e) Rejection-Rezai

Independent claims 124, 143 and 162 are each patentable over Rezai under 35 U.S.C. §§ 102 and 103. To better understand the distinctions between these claims and Rezai, the following remarks set forth the features disclosed in Rezai and the subject matter of these independent claims.

1. Rezai is Directed Toward Methods of Treating a Psychiatric Disorder at a Predetermined Stimulation Site in the Frontal Cerebral Cortex that is Selected from a Large Sampling of Patients with the Particular Disorder

Rezai is directed toward a method for treating psychiatric disorders using chemical and/or electrical neuromodulation. Rezai discloses treating psychiatric

disorders in two separate stages. The first stage is identifying a common region of the orbital frontal cortex that exhibits pathological electrical and/or chemical activity during manifestations of a specific psychiatric disorder from a large sampling of patients that each exhibit the specific psychiatric disorder. (Column 5, lines 8-12.) The common region of the orbital frontal cortex associated with the particular pathological activity of the specific psychiatric disorder constitutes the predetermined treatment site for applying electrical and/or chemical stimulation. (Column 5, lines 12-14.) The second stage includes implanting an electrical stimulator and/or drug-delivery catheter at the predetermined treatment site. Rezai emphasizes that the predetermined treatment site must be within the orbital frontal cortex of the frontal cerebral cortex region to treat the relevant psychiatric disorders. Therefore, Rezai is limited to methods that require a predetermined treatment site in the orbital frontal cortex that is determined by clinically identifying a common area in a large sampling of patients where deviations in normal electrical and/or metabolic neural activity related to the psychiatric disorder occur. Rezai is further limited to placing the electrodes at the site of pathological activity associated with the psychiatric disorder.

2. Rezai Fails to Disclose or Suggest (a) Selecting a Specific Treatment Site for a Specific Patient from Images of the Specific Patient or (b) a Stimulation Site at a Different Location Than the Area of Pathological Neural Activity

Claim 124 is patentable over Rezai because Rezai fails to disclose or suggest several features of this claim. For example, Rezai fails to disclose or suggest selecting a stimulation site of a specific patient based on an image of the neural activity of the specific patient. In contrast to claim 124, Rezai does not select a stimulation site based upon an image of neural activity specific to the brain of a specific patient, but rather Rezai requires determining a treatment site by identifying a common region of the orbital frontal cortex that exhibits pathological electrical and/or chemical activity during manifestations of a specific psychiatric disorder among a large sampling of patients that each exhibit the psychiatric disorder. Therefore, claim 124 is patentable over Rezai.

Claim 143 is patentable over Rezai because this reference fails to disclose or suggest selecting a stimulation site at a region of the cortex that is not where

pathological activity is occurring. Claim 143 includes selecting a stimulation site at a different location from where the brain has been impaired. Rezai teaches directly the opposite of claim 43 because Rezai requires that the "common regions demonstrating [the] pathological activity constitute the predetermined treatment site." (Column 5, lines 13 and 14.) Rezai, therefore, not only fails to disclose this feature of claim 143, but Rezai in fact teaches away from the claimed combination of features of claim 143. Claim 143 is accordingly patentable over Rezai.

Claim 162 is patentable over Rezai because this reference fails to disclose or suggest selecting a stimulation site that is spaced apart from the affected area of the cortex. Rezai only teaches that the feature of the stimulation site be at the pathological area (i.e., the affected site). Claim 162, therefore, is patentable over Rezai.

Claims 125, 126, 131, 132, 136-142, 144, 145, 150, 151, 155-161, 163 and 164 are patentable over Rezai under 35 U.S.C. §§ 102 and 103 as depending from one of the patentable independent claims 124, 143 or 162. Additionally, these dependent claims are further patentable over Rezai because they include additional patentably distinct features. Therefore, the rejection of claims 124-126, 131, 132, 136-145, 150, 151 and 155-164 over Rezai under 35 U.S.C. § 102 should be withdrawn.

B. Response to Section 103 Rejection-Rezai

Claims 133-135 and 152-154 are patentable over Rezai under 35 U.S.C. § 103 as depending from patentable independent claims 124 and 143, respectively. Moreover, claims 133-135 and 152-154 are patentable for the additional features recited in these claims. Therefore, the rejection of claims 133-135 and 152-154 over Rezai should be withdrawn.

C. Allowable Subject Matter

Claims 165-167 have been allowed, and thus these claims have not been amended in this paper. Claims 127-130 and 147-149 were indicated as being allowable if rewritten in independent form. Claim 127 has been rewritten in independent form, and claims 128-130 have been amended to depend from claim 127. Claim 147 has been amended to be an independent form, and claims 148 and 149 have been amended to

depend from claim 147. Therefore, claims 127-130 and 147-149 are condition for allowance.

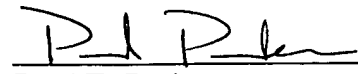
D. New Claims

New claims 168-173 have been added to the present application. Claim 168 is patentable over Rezai because this reference fails to disclose or suggest selecting a stimulation site where neuroplasticity is expected to occur to carry out the desired neural-function. Claim 169 is patentable over Rezai because this reference fails to disclose or suggest placing an electrode at the premotor cortex, motor cortex and/or sensory cortex. Instead, Rezai requires placing an electrical stimulation device only at the orbital frontal cortex to treat psychiatric disorders; Rezai accordingly teaches away from placing electrodes at the premotor cortex, motor cortex and/or sensory cortex as set forth in claim 169. Claims 170 and 173 are patentable over Rezai because this reference teaches away from assessing a symptom of a stroke or movement disorder, and selecting a stimulation site based upon the selected symptom. Therefore, new claims 168-173 are also patentable over Rezai.

In view of the foregoing, the pending claims comply with 35 U.S.C. § 112 and are patentable over the cited art. The applicant accordingly requests reconsideration of the application and a Notice of Allowance. If the Examiner has any questions or believes a telephone conference would expedite prosecution of this application, the Examiner is encouraged to call at (206) 359-3258.

Respectfully submitted,  
Perkins Coie LLP

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Paul T. Parker  
Registration No. 38,264

**Correspondence Address:**

Customer No. 25096  
Perkins Coie LLP  
P.O. Box 1247  
Seattle, Washington 98111-1247  
(206) 359-8000